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Datasheet for the decision of 8 November 2017

Case Number: T 1868/16 - 3.3.01

Application Number: 10175197.2

Publication Number: 2275103

IPC: A61K31/436, A61P35/00, A61P35/04, A61K38/31, A61K45/06

Language of the proceedings: EN

Title of invention:
mTOR inhibitors in the treatment of endocrine tumors

Patent Proprietor:
Novartis AG

Opponents:
Teva Pharmaceutical Industries Ltd.
Synthon B.V./Genthon B.V.
Ethypharm
Maiwald Patent- und Rechtsanwaltsgesellschaft mbH
Generics [UK] Limited (trading as Mylan)

Headword:
Everolsimus/NOVARTIS

Relevant legal provisions:
EPC Art. 83
RPBA Art. 12(4), 13(1)

Keyword:

Sufficiency of disclosure - main request (no)
Auxiliary requests submitted with reply to the statment of grounds of appeal - admitted (yes)
Late filed auxiliary request 6 - admitted (no)
Sufficeincy of disclosure - auxiliary requests (no)

Decisions cited:

T 0609/02, T 0715/03, T 0433/05, T 0801/06, T 0108/09, T 0801/10, T 0134/11, T 0823/11, T 0895/13, T 0950/13, T 1125/13

Catchword:

Europäisches Patentamt
European Patent Office
Office européen des brevets

Beschwerdekammern

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Case Number: T 1868/16 - 3.3.01

D E C I S I O N
of Technical Board of Appeal 3.3.01
of 8 November 2017

Appellant 1: (Opponent 1)	Teva Pharmaceutical Industries Ltd. 5 Basel Street P.O. Box 3190 49131 Petah Tiqva (IL)
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Appellant 2: (Opponent 2)	Synthon B.V./Genthon B.V. Microweg 22 6545 CM Nijmegen (NL)
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Appellant 3: (Opponent 3)	Ethypharm 194 Bureaux de la Colline Bât D 92213 Saint-Cloud (FR)
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Appellant 4: (Opponent 5)	Generics [UK] Limited (trading as Mylan) Albany Gate Darkes Lane Potters Bar Hertfordshire EN6 1AG (GB)

Representative:	Gilani, Anwar Venner Shipley LLP Byron House Cambridge Business Park Cowley Road Cambridge CB4 0WZ (GB)
Respondent: (Patent Proprietor)	Novartis AG Lichtstrasse 35 4056 Basel (CH)
Representative:	Marshall, Cameron John Carpmaels & Ransford LLP One Southampton Row London WC1B 5HA (GB)
Party as of right: (Opponent 4)	Maiwald Patent- und Rechtsanwaltsgesellschaft mbH Jungfernstieg 38 20354 Hamburg (DE)
Representative:	Hamm&Wittkopp Patentanwälte PartmbB Jungfernstieg 38 20354 Hamburg (DE)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 28 June 2016 rejecting the opposition filed against European patent No. 2275103 pursuant to Article 101(2) EPC.**

Composition of the Board:

Chairman	A. Lindner
Members:	G. Seufert
	L. Bühler

Summary of Facts and Submissions

I. Opponents 1, 2, 3 and 5 (appellants 1 to 4) lodged an appeal against the decision of the opposition division rejecting the oppositions against European patent No. 2 275 103.

II. The patent was granted on the basis of 15 claims. Independent claims 1 and 8 read as follows:

"1. 40-O-(2-hydroxyethyl)-rapamycin for use in a treatment of pancreatic neuroendocrine tumor."

"8. 40-O-(2-hydroxyethyl)-rapamycin for use in a treatment of pancreatic neuroendocrine tumor invasiveness."

Independent claims 14 and 15 are directed to a pharmaceutical composition comprising 40-O-(2-hydroxyethyl)-rapamycin for use in the treatment of pancreatic neuroendocrine tumor and pancreatic neuroendocrine tumor invasiveness.

III. The present decision refers to the following documents:

(6) J. C. Yao *et al.*, The New England Journal of Medicine, 364(6), 2011, pages 514 to 523

(14) G. von Wichert *et al.*, Cancer Research, 60, 2000, pages 4573 to 4581

(19) Novartis International AG, "Pivotal Phase III trial of Novartis drug Afinitor® met primary endpoint in study of patients with advanced pancreatic neuroendocrine tumors" Media release, 2010, pages 1 to 4

(25) K. Öberg *et al.*, Acta Oncologica, Vol. 43, No. 7, 2004, pages 617 to 625

(30) ClinicalTrials.gov archive "View of NCT00113360 on 2005_08_01", Study Protocol, pages 1 to 4

(49) J. C. Yao *et al.*, Journal of Clinical Oncology, 2006 ASCO Annual Meeting Proceedings, Vol. 24, No. 18S, 2006, abstract 4042, one page

(55) J. E. S. Ardill, B. Erikkson, Endocrine-Related Cancer, 10, 2003, pages 459 to 462

(56) J. C. Yao *et al.*, Journal of Clinical Oncology, 26, 2008, pages 4311 to 4318

(57) E. Liu *et al.*, Therapeutic Advances in Gastroenterology, 6(5), 2013, pages 412 to 419

(59) Novartis AG, "Novartis drug Afinitor is first treatment for advanced pancreatic NET to provide overall survival of more than 3.5 years in Phase III trial, Media release, 2014, pages 1 to 9

(74) Afinitor Tablets, Summary of Product Characteristics Updated 07-Apr-2015, Novartis Pharmaceuticals UK Ltd, obtainable from http://www.medicines.org.uk/emc

(75) A. Göndör *et al.*, European Journal of Endocrinology, 148, Suppl. 1, 2003, abstract 303, one page

(76) Oxford Advanced Learner's Dictionary of Current English, 5th edition, Ed. Jonathan Crowther, Oxford Press, page 691, definition of "may", one page

(77) Läkemedelsverket, Medical Products Agency, Summary Public Assessment Report, Certican (Everolismus), last update 2014-11-18, three pages

(78) I. Duran *et al.*, Developemental Therapeutics: Molecular Therapeutics, abstract 3096, one page

(79) I. Ruvinsky *et al.*, Genes & Development, 19, 2005, pages 2199 to 2211

(80) I. Duran *et al.*, British Journal of Cancer, 95, 2006, 1148 to 1154

(81) Exhibits A to D filed by appellant 1 with letter dated 15 November 2016 in support of its request for acceleration of the proceedings

(82) Exhibits E, F and English translation of Exhibit D filed by appellant 1 with letter dated 16 February 2017 in further support of its request for acceleration of the proceedings

IV. Notices of opposition were filed by opponents 1 to 5 requesting revocation of the patent in suit in its entirety on the grounds of lack of novelty, lack of inventive step, insufficiency of disclosure and added subject-matter (Article 100(a), (b) and (c) EPC). Opponent 5 also requested revocation on the ground of exclusion to patentability pursuant to Article 53(c) EPC.

V. In the decision under appeal, the opposition division held that none of the grounds for opposition prejudiced the maintenance of the patent in suit in unamended form.

According to the opposition division, the requirements of Articles 123(2), 76(1) and 53(c) EPC were not contravened. There was no lack of sufficiency of disclosure, since it had been plausibly demonstrated in the patent in suit (see point D, in particular paragraphs [0052] and [0053]) that 40-O-(2-hydroxyethyl)-rapamycin (hereinafter everolismus) could be used in the treatment of pancreatic neuroendocrine tumours (hereinafter PNETs), which was further supported by post-published evidence.

The subject matter of the claims was novel and involved an inventive step starting from document (30) as the closest prior art. The technical problem was formulated

as the provision of an alternative, efficacious medicament for the treatment of PNETs. According to the opposition division the skilled person had no reasonable expectation of success given the very high failure rate of cancer drugs and the knowledge that PNETs were particularly difficult to treat.

VI. In their statements setting out the grounds of appeal, appellants 1 to 4 maintained their objections of added subject-matter, insufficiency of disclosure, lack of novelty and lack of inventive step.

VII. With letter of 15 November 2016, appellant 1 requested acceleration of the appeal proceedings, which the board did not accede to for reasons set out in its communication of 6 December 2016.

VIII. With letter dated 16 February 2017, appellant 1 maintained its request for acceleration and submitted further arguments and evidence in reply to the board's communication of 6 December 2016.

IX. In a communication dated 27 February 2017, the board informed the parties of its intention to accede to appellant 1's request for acceleration.

X. In its reply to the statements of grounds of appeal dated 21 March 2017, the respondent (patent proprietor) defended the patent in suit as granted (main request). In addition, it filed auxiliary requests 1 to 8. Auxiliary requests 6 to 8 were subsequently renamed auxiliary requests 7 to 9 (see point XII below). Finally, auxiliary requests 1, 2 and 9 were withdrawn (see point XIV below).

Auxiliary request 3 differs from the main request in that the feature **"wherein 40-O-(2-hydroxyethyl)-rapamycin is used in an amount of 5 mg or 10 mg daily in monotherapy"** has been added to claims 1, 8 and 10 (granted claim 14). Claims 10 to 13 and 15 as granted have been deleted.

Auxiliary request 4 differs from the main request in that the feature **"wherein 40-O-(2-hydroxyethyl)-rapamycin is used in an amount of 10 mg daily"** has been added to claims 1, 8, 14 and 15.

Auxiliary request 5 differs from auxiliary request 3 in that the amount of 40-O-(2-hydroxyethyl)-rapamycin in claims 1, 8 and 10 has been restricted to **10 mg**.

Auxiliary request 7 (previous auxiliary request 6, filed with letter dated 21 March 2017) contains 2 claims, wherein claim 1 reads as follows:

"1. 40-O-(2-hydroxyethyl)-rapamycin for use as a monotherapy in the treatment of advanced pancreatic neuroendocrine tumor after failure of cytotoxic chemotherapy, wherein 40-O-(2-hydroxyethyl)-rapamycin is to be administered at a dose of 10 mg/day."

Auxiliary request 8 (previous auxiliary request 7, filed with letter dated 21 March 2017) differs from the main request in that the feature **"wherein the pancreatic neuroendocrine tumor is selected from the group consisting of: APUDomas, insulinomas, glucagonomas, nonfunctioning pancreatic NETs, pancreatic NETs associated with hypercalcemia, gastrinomas, VIPomas, somatostatinomas and GRFomas"** has been added to claims 1, 6 (granted claim 8), 12 and 13

(granted claims 14 and 15). Claims 2 and 4 as granted have been deleted.

XI. With letters of 8 September 2017 (appellant 4), 6 October 2017 (appellants 1 and 2) and 6 November 2017 (appellant 1), appellants 1, 2 and 4 submitted further arguments and evidence in support of their cases.

XII. With letter of 27 October 2017, the respondent filed a new auxiliary request 6. The previous auxiliary request 6 was maintained as auxiliary request 7 and previous auxiliary requests 7 and 8 were maintained as auxiliary requests 8 and 9 (see point X above).

Auxiliary request 6 differs from the main request in that all claims have been limited to the treatment of **advanced** pancreatic neuroendocrine tumor.

XIII. With letter dated 7 November 2017, opponent 4, party as of rights, who took no active part in the appeal proceedings, informed the board that it would not be attending the oral proceedings.

XIV. At the oral proceedings before the board, the respondent withdrew auxiliary requests 1, 2 and 9.

XV. The appellants' arguments, as far as they concern the decisive issues of the present decision, can be summarised as follows:

- Acceleration of the proceedings

Acceleration of the proceedings was requested in accordance with the Notice from the Vice-President Directorate-General 3 dated 17 March 2015 (OJ EPO, 2008, 220). The patent proprietor had instituted

arbitration proceedings, which were *de facto* infringement proceedings, against Teva B.V. in Portugal (see Exhibit A) and threatened to request a conviction to the payment of a compensation for alleged damages, which represented actual and substantial risks for appellant 1. From Exhibits B and C it was apparent that appellant 1 was the sole shareholder and board member of Teva B.V. It therefore had a direct and immediate interest in the outcome of the Portuguese arbitration proceedings.

According to Portuguese Law 62/2011 arbitration proceedings were mandatory (see Exhibit E, page 2). Such mandatory arbitration could include preliminary injunction proceedings pursuant to Article 2 of the Law 62/2011 (see Annex II of Exhibit E). This was also apparent from Exhibit A (see page 2). It was also explained in Exhibit E that there was a high degree of uncertainty, whether the Portuguese arbitration tribunal would have jurisdiction to assess invalidity arguments (see pages 5 to 6). There was therefore a risk that the patent proprietor would take advantage of the current uncertainty to the effect that unjustified injunctive measure might be awarded and maintained over an extended period of legal uncertainty, while the defendant (appellant 1) would be barred from raising invalidity in defence.

While the award issued by the arbitration, which in a "worst-case" scenario could be decided about mid-2017, was appealable to the Second Instance Court, such an appeal could not stay the arbitration court decision. Thus, in the "worst case" scenario, a possible injunction would be in place while the appeal proceedings were on-going and could only effectively be overturned after the EPO had revoked the patent for

invalidity should the arbitration court refuse to assess validity. Appellant 1 had requested a decision by the end of 2017 beginning of 2018, because this was considered to be a realistic time frame. This did not mean that the acceleration would not have any practical impact for the situation in Portugal. Moreover, as was explained in Exhibit E, the Portuguese Arbitration Act (LAW No. 63/2011), which the arbitration courts have been following, also provided for a possible extension of the deadline for the delivery of the award (see pages 4 to 5). An on-going appeal before the EPO might also be a justifiable ground for a stay of the arbitration proceedings in Portugal and for postponement of the delivery of the final award (see Exhibit E, Page 5).

Regardless of whether the final arbitral award was delivered within the 12 months or after an additional extension, or whether arbitral proceedings would be stayed, the timing of the decision in the present appeal would be the decisive factor for any actual and practical consequence taking effect and being maintained over an uncertain period of time.

The fact that also other right were mentioned in Exhibit A was not relevant. It was not uncommon that in arbitration proceedings the patent proprietor seeks enforcement of a whole bundle of patents. Access to accelerated proceedings should not be denied as a patent proprietor could otherwise escape from any acceleration by simply asserting more than one patent in local arbitration proceedings. Appellant 1 had outlined the urgency in the present case. Any further assessment involving a prospective and comparative assessment of a multitude of specific patent rights exceeded, by far, the scope of the analysis normally

required for a request of acceleration of appeal proceedings.

- Sufficiency of disclosure (main request)

The requirement of sufficiency of disclosure was not met. For a claim directed to a second medical use, the application must provide a credible disclosure which allowed the conclusion that the claimed treatment was achieved. No data of any kind that could demonstrate the suitability of everolismus in the treatment of PNETs was present in the application. All clinical trials referred to in point D (paragraphs [0052] to [0056] of the patent in suit) were hypothetical clinical study projects. Paragraphs [0052] and [0053] contained exclusively prophetic statements, which was apparent from the wording being used, i.e. effects that "may be observed" or evaluations that "may be performed". The reference to the inhibition of S6K1 activity and the reduction of chromogranin A was not an indication that a study had already been carried out or was on-going. Inhibition of S6K1 was an expected pharmacodynamic effect for an mTOR inhibitor and chromogranin A was a known surrogate biomarker, the reduction of which was a desired outcome. Moreover, as was apparent from document (56), which according to the respondent reflected the full trial report of the allegedly on-going clinical study referred to in paragraphs [0052] and [0053], synergistic effects as mentioned in paragraph [0053] could not have been observed, as the study was not designed for this purpose. It was also apparent from document (6) that recruitment for a clinical study of everolismus as a monotherapy of PNETs, to which paragraph [0052] of the patent in suit referred, started more than one and half year after the first priority date, which was a further

indication for the merely prophetic statements made in paragraphs [0052] and [0053].

Furthermore, these paragraphs were unspecific in that they referred to two different types of cancer, namely carcinoid and islet cell cancer. There was no information available for which patients the effects were allegedly observed. Moreover, chromogranin A was not always elevated.

The statements in paragraphs [0052] and [0053] were not supported by documents (49) and (56), allegedly reflecting the clinical trial mentioned in these paragraphs. For example, both documents described solely a combination treatment on a particular advanced form of carcinoid tumours and PNETs, no synergistic effects and no data with respect to the S6K1 activity were disclosed. Moreover, in document (49) reduction of chromogranin A was only reported for 9 out of 18 patients with elevated chromogranin A at baseline. No allocation of this effect to particular patients (i.e. patients with carcinoid tumours or PNETs) was provided.

The respondent asserted that PNETs were particularly difficult to treat, that no mTOR inhibitor was known to treat PNETs and that everolismus was a first in class treatment for PNETs. In these circumstances, it would have been incumbent upon the respondent-patentee to provide data demonstrating the suitability of everolismus in the treatment of PNETs in the application as filed. A mere verbal statement and a reference to effects that may be obtained were not sufficient. Furthermore, for sufficiency of disclosure neither the content of the priority documents nor data that the respondent-patentee may have had, but decided, for whatever reasons, not to disclose, were relevant.

There also was no plausible technical concept, on the basis of which the skilled person could accept that everolismus was suitable in the treatment of PNETs. No link between mTOR inhibition and PNET treatment had been established in the prior art and, according to the respondent, no mTOR inhibitor was known to treat PNETs.

- Admission of auxiliary requests 3, 6 and 8

Auxiliary requests 3 and 8 could have been filed during the opposition proceedings, since objections as to sufficiency of disclosure and lack of inventive step had already been raised in the opposition briefs. Their filing was no reaction to the decision under appeal, which did not rely on new facts or arguments, and no reaction to newly filed document (75), as the information in this document was the same as in document (14), which was part of the opposition proceedings. Moreover, the filing of auxiliary request 3 raised new issues under Article 123(2) EPC. Against the subject-matter of claim 1 of auxiliary request 8 (based on claim 2 as granted) an objection of added subject-matter had already been raised in the notice of opposition of appellant 2.

Auxiliary request 6 was filed at a very late stage in the appeal proceedings without justification. The focus on document (75), which had been filed with the statement of grounds of appeal, had not changed in the course of the proceedings. Nor was it apparent as to how the introduction of the term "advanced" specifically addressed the allegedly new arguments of appellants 1, 2 and 4.

- Sufficiency of disclosure (auxiliary requests 3 to 5, 7 and 8)

Essentially, the same arguments as for the main request applied for auxiliary requests 3 and 4. There was no evidence in the application as to the suitability of everolismus in the treatment of PNETs.
Paragraphs [0054] and [0056], on which the respondent relied, were admittedly clinical studies, which had not yet been carried out and therefore had not provided any results at the priority date. Providing information as to the amount of everolismus to be used in future studies could not cure the fact that these studies had not yet happened. The situation in the decisions on which the respondent relied was factually different as some data or at least a plausible technical concept had been available. Document (59), which allegedly reflected the study mentioned in paragraph [0056] of the patent, was published about nine years after the priority date and could not remedy the lack of sufficiency of disclosure.

The same arguments as for the previous requests applied to auxiliary requests 5, 7 and 8.

XVI. The respondent's arguments, as far as they concern the decisive issues of the present decision, can be summarised as follows:

- Acceleration of appeal proceedings

The appeal proceedings should not be accelerated, as such acceleration had no meaningful impact in the Portuguese arbitration proceedings, on which appellant 1 relied as a justification for its request.

The appellant's statement that acceleration was decisive for the ultimate outcome and the extent of the economic and practical consequences of the proceedings in Portugal was rejected, because other patents protected everolismus until 2019. Even if appellant 1's appeal succeeded, it could not launch its product in Portugal.

Exhibit A was redacted. The redacted text included granted European Patent No. 663 916, which protected everolismus as a product. This patent expired in September 2013, but protection of everolismus had been extended until July 2018 using the supplemental protection certificate (SPC) system. This SPC was also within the arbitration proceedings and was also redacted from Exhibit A. The term of the SPC was itself subject to a six months extension under the EU Paediatric Regulation, which led to an expiry date for product protection of 18th January 2019 in Portugal. This SPC meant that a decision in this appeal before the end of 2018 was irrelevant in Portugal. Even if appellant 1's appeal succeeded, the Portuguese arbitration proceedings would always continue based on the SPC.

Appellant 1 also stated that the arbitration proceedings might already be completed in mid-2017, but even if they finished later, it was unlikely that they would drag out into 2019, beyond the expected expiry of the SPC in Portugal. The timetable of the arbitration confirmed that acceleration of the EPO appeal proceedings had no meaningful impact on the result of the Portuguese arbitration proceedings.

- Sufficiency of disclosure (main request)

The patent in suit disclosed in paragraphs [0052] and [0053] a clinical study that was underway and that had already provided data at the earliest priority date. Recruitment had started in February 2007 (see document (49)). Evaluation every 12 weeks meant that at the earliest priority date 3 sets of data were already available. The actual numbers were present in the priority documents, including the earliest priority document, which were available at the filing date of the patent and in document (49), which was published between the earliest priority date and the filing date. The study tested the effect of everolismus and Sandostatin on islet cell cancer (i.e. PNETs) and on carcinoid tumours. As explained in paragraph [0052] of the patent in suit, inhibition of S6K1 activity and a reduction of chromogranin A had been observed, which demonstrated that a therapeutic effect had been achieved with everolismus. The claimed subject-matter was not based on mere hypothesis, but on concrete clinical data. Paragraphs [0052] and [0053] were not mere verbal statements, but supported the claimed therapeutic use by "*information in the form of .... experimental test*" in accordance with the requirements explained in point 9 of T 609/02.

The *in vivo* results reported in paragraph [0052] clearly showed a credible effect for everolismus. The term "may" in this paragraph was used as a permissive word to indicate that inhibition of S6K1 activity and reduction of chromogranin A would be seen when they were looked for. It was not used in a speculative way. The technical content of a patent and the sufficiency of its teaching were not dependent on such inconsequential stylistic preferences of the drafting patent attorney.

Paragraphs [0052] and [0053] described specific details regarding the clinical study (dosing) and specific results. This could not reasonably be interpreted as merely theoretical and aspirational, but proved that the results had been obtained from the study. Paragraphs [0052] and [0053] had to be contrasted with paragraphs [0054] to [0056], which described future trials.

It was established jurisprudence of the boards of appeal that for sufficiency of disclosure of a second medical use claim it was not necessary to include the final therapeutic results of a clinical study. For example, decision T 433/05 explained in point 28 of the reasons that "*for acceptance of a sufficient disclosure of a therapeutic application in a patent/patent application, it is not always necessary that results of clinical trials are provided at the relevant date, but that it is required that the patent/patent application provides some information to the avail that the claimed compound has a direct effect on a metabolic mechanism specifically involved in the disease*". Similarly, T 801/06 explained in point 28 of the Reasons that "*a claimed therapeutic effect may be proven by any kind of data as long as they clearly and unambiguously reflect the therapeutic effect*". According to T 801/10 the observed effect must directly and unambiguously reflect the therapeutic application. Paragraphs [0052] and [0053] reported that inhibition of S6K1 activity and reduction of chromogranin A were observed when everolismus was administered to patients with PNETs, which was clear and unambiguous evidence that everolismus had positive therapeutic and pharmacodynamic effects on PNETs.

Chromogranin A was an established biomarker for measuring the efficacy of PNET treatment and the best general marker for neuroendocrine tumours, as was apparent from document (55) (see abstract, page 460, left column, lines 6 to 10). It was known that chromogranin A was elevated in patients with neuroendocrine tumours (see documents (55) and (25)). *In vivo* reduction of chromogranin A was clear and unambiguous evidence that a therapeutic effect had been achieved.

The observed inhibition of S6K1 activity reflected the immediate pharmacodynamic effect of mTOR inhibitors and showed that everolismus successfully inhibited downstream targets of mTOR as explained in paragraph [0048] of the patent in suit. These data confirmed that everolismus had a direct effect on a metabolic mechanism relevant to PNETs. Octreotide (Sandostatin LAR®) had no effect on S6K1 and a very low tumour response rate.

The credible disclosure in the patent in suit was confirmed by post-published evidence (see documents (6), (19), (49), (56) and (74)). The study that first reported efficacy of everolismus to treat PNETs was the study disclosed in paragraphs [0052] and [0053] of the patent in suit. The full trial results were reported in document (56). This document reiterated the findings regarding inhibition of S6K1 activity and chromogranin A reduction of the patent (see page 4314, left-hand column, first paragraph and page 4316, right-hand column, second paragraph) and provided further confirmatory data from the end of the trial.

Documents (6) and (19) reported on the results of the phase III "Radiant-3" study, which generated the data that led to the approval of everolismus for treating PNETs. However, a review of the relevant literature confirmed that the study first reported in paragraphs [0052] and [0053] of the patent and then in document (56) was the breakthrough work that first showed efficacy of everolismus in PNET treatment (see document (57), page 415, right-hand column, second paragraph). Document (74) further confirmed the suitability of everolismus in the treatment of PNETs.

Document (49) was the same trial as the one reported in paragraphs [0052] and [0053]. There was only one trial on-going. It was expanded to a wider group of patients and the full trial results were reported in document (56). There was a direct link from the earliest priority document with its results to document (49) and finally document (56).

- Admission of auxiliary requests 3, 6 and 8

Auxiliary requests 3 and 8 should be admitted. Like all auxiliary requests submitted with the reply to the statements of grounds of appeal, they were filed in response to new document (75) filed by appellant 1 with its statement of grounds of appeal. A *prima facie* basis for the amendment in the application as originally filed had been provided for each of these requests.

Auxiliary request 6 was filed in response to new arguments from appellants 1, 2 and 4 focussing on document (75). In the statement of grounds of appeal, appellant 1 had provided only brief comments and explanations with regard to this document.

- Sufficiency of disclosure (auxiliary requests 3 to 5, 7 and 8)

With regard to auxiliary request 3, the following was added. From paragraph [0052] the skilled person derived a clear technical disclosure that everolismus was suitable for the treatment of PNETs. If he was still in doubt, there was further information provided in paragraphs [0054] and [0056] to enable him to carry out the invention. Paragraph [0054] mentioned suitable doses of everolismus and paragraph [0056] clearly identified the patients as patients with PNETs and the administration of everolismus as monotherapy. The skilled person just had to follow these instructions and carry out the clinical trial as disclosed in paragraph [0056]. In this context reference was made to decision T 108/09, in which the board found that no specific example was necessary, since the application contained detailed information as to how the invention should be put into practice. Decisions T 715/03 and T 950/13 were also referred to. In the latter decision the board acknowledged sufficiency of disclosure in the absence of any clinical data.

Claim 1 of auxiliary request 4 was limited to an everolismus dose of 10 mg per day. This was the most effective dose and led to unprecedented results, as was apparent from document (59). The details in document (59) matched paragraph [0056] (see page 3, line 10).

No additional arguments were provided for auxiliary requests 5, 7 and 8.

XVII. The appellants 1 to 4 requested that the decision under appeal be set aside and that the patent be revoked.

Appellants 1, 2 and 3 further requested that auxiliary request 6 filed with letter dated 27 October 2017 not be admitted into the appeal proceedings. Appellant 1 also requested that document (79) not be admitted into the appeal proceedings. Appellant 2 further requested that auxiliary requests 1 to 3 filed with letter dated 21 March 2017 and auxiliary requests 8 and 9 filed as auxiliary requests 7 and 8 with letter dated 21 March 2017 not be admitted into the appeal proceedings and that document (80) be admitted into the appeal proceedings.

XVIII. The respondent requested that the appeals be dismissed (main request), or, alternatively, that the patent be maintained on the basis of the claims of one of the following requests:

- auxiliary requests 3 to 5 filed with letter dated 21 March 2017;
- auxiliary request 6 filed with letter dated 27 October 2017; and
- auxiliary requests 7 and 8 filed as auxiliary requests 6 and 7 with letter dated 21 March 2017.

The respondent further requested that the written decision includes the reasons for accelerating the proceedings and explains the distinction between the present case and decision T 950/13 of the same board.

The respondent further requested that documents (75) to (78) not be admitted into the appeal proceedings.

XIX. Opponent 4, party as of right, did not file any requests in writing.

XX. At the end of the oral proceedings the decision of the board was announced.

Reasons for the Decision

1. The appeal is admissible.

2. As communicated in advance to the board (see point XIII above), opponent 4 and party as of rights, who did not submit any comments or observations with regard to the substantive issues, did not attend the oral proceedings before the board to which it had been duly summoned. The board decided to continue the proceedings pursuant to Rule 115(2) EPC and Article 15(3) RPBA.

3. Accelerated processing

3.1 As a preliminary remark which, however, is not relevant for the present decision, the board would like to note that it regards acceleration of the appeal proceedings as well as postponement of oral proceedings to be matters pertaining to the conduct of the appeal proceedings which lies within the sole competence of the board. It might therefore be questioned whether the grant or refusal of a request for acceleration or postponement is at all a decision within the meaning of Article 111 EPC for which the board has to give its reasons pursuant to Rule 102 g) EPC. Nevertheless, in the present case, the board agreed to respond to the respondent's request for being given the board's reasons on acceleration.

3.2 It goes without saying that the board has to ensure the proper administration of justice by way of a fair,

orderly and efficient conduct of the proceedings. With respect to the parties' rights relevant for the conduct of the appeal proceedings, the board notes that the parties have a right that their case be decided "within a reasonable time" (Article 6(1) of the European Convention on Human Rights (ECHR); see T 823/11 of 21 December 2015, point 2). There is no right to have proceedings delayed. Furthermore, due respect to the parties' right to be heard has to be given. This is also explicitly stated in the Notice from the Vice-President Directorate-General 3 dated 17 March 2015 (OJ EPO, 2008, 220; hereinafter referred to as notice) which is taken into account by the board when considering a request for acceleration.

3.3 According to the notice, parties with a legitimate interest may ask the boards of appeal to deal with their appeals rapidly. The notice mentions situations which could justify such acceleration. However, acceleration is not limited to those exemplified situations and is a matter to be decided at the discretion of the board on the particular facts of the case before it (see e.g. decision T 895/13 and T 1125/13 of 28 March 2014, Reasons 10). While trivial reasons would clearly not justify acceleration, it follows from the scenarios exemplified in the notice that the term "legitimate interest" is not to be construed as requiring compelling reasons. Rather, objective reasons have to be put forth that warrant giving the appeal priority.

3.4 In the present case, appellant 1 requested acceleration of the appeal proceedings on the grounds that arbitration proceedings had been brought against an affiliate company in Portugal.

3.4.1 In view of the additional information and evidence filed by appellant 1 with its letter dated 16 February 2017 regarding the legal nature of the arbitration proceedings pursuant to Portuguese law No. 62/2011 of 12 December 2011 (document (82), Exhibit E), the board was satisfied that the national proceedings in Portugal, albeit relying on arbitration, were mandatory and not merely voluntary and could thus be considered *de facto* as infringement proceedings as argued by the appellant 1 (see point XV above). In the board's judgement, the arbitration proceedings which had been instituted in Portugal were thus circumstances that could justify acceleration as explicitly acknowledged in the notice.

3.4.2 From Exhibit A of document (81) and Exhibit D (see translation filed with letter dated 16 February 2017, document (82)) it is apparent that the patent in suit - i.e. European patent No. 2 275 103 - has been invoked in the arbitration proceedings in Portugal. The respondent argued, however, that the arbitration proceedings were based on several intellectual property rights (namely European Patent No. 663 916 and a supplemental protection certificate (SPC) extending the protection conferred by said patent until July 2018) which protected everolismus as a product and served as independent basis for the infringement action. Therefore, a ruling on European patent No. 2 275 103 in the present appeal proceedings had no bearing on the arbitration proceedings which would in any case continue. The board agrees with appellant 1 that it is not appropriate for the purpose of deciding on accelerated processing to embark on a more thorough enquiry into the practical or economic impact of the present appeal proceedings on the arbitration proceedings in Portugal. Indeed, such an analysis would

entail a prospective investigation into the arguments, in the infringement proceedings, relying on the patent in suit. Such considerations would clearly exceed the scope of analysis required for deciding on a procedural request for accelerated processing. In view of the fact that the patent in suit has been relied on in the national arbitration proceedings as independent basis for the infringement action and that in this respect the present appeal proceedings are of relevance, even possibly only to a limited extent, for the national arbitration proceedings, the board is satisfied that there were legitimate reasons for giving the present appeal priority.

3.4.3 Finally, while the arbitration proceedings in Portugal have been brought against an affiliate and not against appellant 1, the board judges that it is sufficient to show that a party to the present proceedings belongs to the same group of companies in order to establish a legitimate interest within the meaning of the notice. Indeed, the notice does not establish a requirement for the parties to appeal proceedings to be party to national infringement proceedings in order to request accelerated processing.

3.4.4 For the above reasons, the board gave priority to the present appeal.

Main request

4. Sufficiency of disclosure

4.1 Claim 1 of the main request is a purpose-related compound claim pursuant to Article 54(5) EPC directed to 40-O-(2-hydroxyethyl)-rapamycin for use in the treatment of pancreatic neuroendocrine tumours.

In the decision under appeal sufficiency of disclosure was acknowledged. This decision was challenged by appellants 1 to 4, who maintained their position that technical data or a plausible technical concept, which could demonstrate the suitability of everolismus in the treatment of PNETs, was missing.

4.2 Pursuant to Article 83 EPC, a patent shall disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art.

In relation to claims directed to a second medical use, it is established jurisprudence of the boards of appeal that, for Article 83 EPC to be complied with, unless this is already known to the skilled person at the priority date, the application must disclose the suitability for the claimed therapeutic use (see T 609/02, point 9 of the Reasons; T 433/05, point 28 of the Reasons; T 801/06, point 25 of the Reasons). Clinical data are not always required. Mere verbal statements are however not enough. The patent application must provide some information in the form of, for example, experimental tests to the avail that the claimed compound has a direct effect on a metabolic mechanism specifically involved in the disease. *In vitro* examples may be sufficient, if for the skilled person they directly and unambiguously reflect the therapeutic application. Post-published evidence may be taken into account, but only to back-up the findings in the application (cf. T 609/02, point 9 of the Reasons).

It follows from the above that in the present case it has to be examined whether the suitability of everolismus for the treatment of patients with PNETs

has been shown or at least made plausible in the application taking into account the common general knowledge of the person skilled in the art.

4.3 As evidence of the suitability of everolismus in the treatment of PNETs, the respondent relied solely on paragraphs [0052] and [0053] of the patent in suit (page 37, lines 1 to 7 of the application as filed). According to the respondent, these paragraphs described a then on-going clinical study and the results that had been observed, namely the inhibition of S6K1 activity and the reduction of chromogranin A (see point XVI above). The disclosure of paragraphs [0052] and [0053] was to be contrasted with paragraphs [0054] to [0056] which described future trials. The post-published documents (6), (19), (49), (56) and (74), in particular documents (49) and (56) confirmed the disclosure in the paragraphs [0052] and [0053].

4.4 The board does not agree.

4.4.1 Paragraph [0052] mentions that in clinical trial studies involving patients having carcinoid or islet cell cancer (the latter is equivalent to PNET, according to column 1, lines 33 and 34 of the patent in suit and page 3, lines 21 and 22 of the application or to a specific type of PNET, according to column 4, lines 2 to 6 of the patent in suit and page 11, lines 15 to 17 of the application) inhibition of S6K1 activity and a reduction of chromogranin A may be observed when administering everolismus alone or in combination with Sandostatin LAR®. Response evaluation may be performed every 12 weeks. No data of any kind is provided. It cannot be ascertained which patients, if any, have actually been treated or what results, if any, have been achieved in patients with PNETs. Nothing

in this paragraph allows the skilled reader to conclude that paragraph [0052] refers to an on-going study, unlike paragraphs [0054] to [0056], which admittedly reflect future trial studies, and that certain effects had indeed been observed, let alone that these effects correlate to a disease response, in particular in patients with PNETs. Paragraph [0052] provides nothing more than hypothetical statements indicating the possibility that some effects may be observed. The respondent's argument that the skilled reader would equate the expressions "may be observed" and "may be performed" with "had been observed" and "had been performed" and that the wording in paragraph [0052] was merely the inconsequential stylistic preference of the person drafting the application is not accepted.

The board also notes that inhibition of S6K1 activity reflects an expected pharmacodynamic effect of an mTOR inhibitor, such as everolismus (see patent in suit, paragraph [0048]). It is not an indication for an effective treatment of PNETs (see also respondent's reply to the statement of grounds of appeal, page 13 footnote 10). Nor is it a clear sign for the skilled person that a clinical trial study was on-going.

Chromogranin A is a universally helpful biomarker for neuroendocrine tumours of the pancreas and gut. It is primarily important for diagnostic purposes. Elevated levels of chromogranin A are found in most patients with metastatic neuroendocrine tumours. It is considered as a helpful indicator of the effectiveness of treatment (see document (55), title, and abstract). It is also considered to be the best general marker for neuroendocrine tumour, particularly of the carcinoid group. In 92% of active gastrinomas (pancreatic neuroendocrine tumours) the level of chromogranin A has

been shown to be elevated (see page 460, left-hand column, lines 6 to 11). None of this is contested by the board. However, chromogranin A reduction only reflects a desired outcome, i.e. one that the skilled person would hope for. The mere statement that chromogranin A reduction may be observed is not an indication that a clinical trial was on-going or that certain effects had actually been achieved. Moreover, in the absence of any information as to whether patients with PNETs have been treated or whether chromogranin A reduction actually correlates with tumour response in these patients, the mere statement that chromogranin A reduction may be observed is not sufficient to demonstrate the suitability of everolismus in the treatment of PNETs. This correlation has apparently been made for the first time in post-published document (56), which states that the observed antitumor activity was supported by changes in biomarkers (see page 4316, right-hand column, lines 10 to 12). Document (49) merely states that of 18 patients with elevated chromogranin A at baseline, 9 patients had >50% reduction without identifying these patients (32 patient were treated, 18 with carcinoid tumours, 13 islet cell cancer) and without any correlation to tumour response.

4.4.2 Paragraph [0053] of the patent in suit consists of a single sentence and states that "also synergistic effects of such combination are obtained" (i.e. the combination referred to in the preceding paragraph). Again this is a mere statement which is not supported by any factual evidence. The board also concurs with appellant 2 that it is questionable whether the set-up mentioned in paragraph [0052], which refers to the administration of everolismus alone or in combination with Sandostatin LAR® is suitable to demonstrate a

synergistic effect, which would also require the administration of Sandostatin LAR® alone. Moreover, document (56), which according to the respondent, reports the full trial results of the on-going trial referred to in paragraphs [0052] and [0053] of the patent, states that synergistic effects were not clear from this single arm study. Thus, contrary to the statement in paragraph [0053], such an effect could not have been observed. Furthermore, as pointed out by the appellants, a trial with everolismus alone had not even started before July 2007 (see document (6), page 517, left-hand column, last paragraph, first sentence).

4.5 The board therefore concurs with the appellants that paragraphs [0052] and [0053] do not make the suitability of everolismus in the treatment of PNETs plausible. The respondent did not rely on any other data or information provided in the patent or patent application.

4.6 What remains to be considered is whether common general knowledge provides the skilled person with a plausible technical explanation which allows him to conclude that everolismus would be suitable for the treatment of PNETs.

In the present case, no such common general knowledge has been relied on by the respondent. On the contrary, according to the respondent, neuroendocrine tumours, in particular PNETs, were difficult to treat and efficacy against different types of cancer was not an indication for efficacy in PNETs. Prognosis for patients with PNETs was poor. Chemotherapeutic treatment of neuroendocrine tumours with cytotoxic agents was apparently of low efficiency (see also patent in suit paragraphs [0005] and [0007] or document (57), page

413, left-hand column, second paragraph). More importantly however, according to the respondent, everolismus was the first mTOR inhibitor to treat PNETs.

It is the board's conviction that in these circumstances, where there existed no established relationship between mTOR inhibition and the treatment of PNETs, it was imperative to provide at least some technical evidence in the application as filed that allowed the skilled person to conclude that everolismus was suitable for the treatment of PNETs. A mere reference to the (desired) reduction of a biomarker that may be observed or a response evaluation that may be performed is not sufficient in this context.

4.7 The respondent's argument that it had been aware of intermediate results showing the suitability of everolismus in the treatment of PNETs, as the trial study reported in document (56) had already been on-going for several months before the earliest priority date, is not accepted. For sufficiency of disclosure, it is not relevant what the respondent was aware of, but decided not to disclose. Rather the application, taking into account common general knowledge, must contain sufficient evidence or at least a technically plausible concept that allowed the skilled person to conclude that the claimed compound is suitable for the claimed therapeutic use. For the reasons set out in points 4.4 and 4.6 above this is not the case here.

Concerning the "data" in the priority documents, the board concurs with the appellants that the content of the priority documents does not form part of the disclosure of the application. Even if they were to be considered, the disclosure in the priority documents is

as insufficient as in the application. The alleged reduction of chromogranin A without any information as to tumour growth regression, progression or stabilisation in the treated patients cannot be considered as evidence that everolismus is suitable in the treatment of PNETs. The board also notes that the statements in the priority documents with regard to the allegedly observed effects (synergistic effect, total inhibition of S6K1, reduction of more than 50% of chromogranin A) are inconsistent with the results provided in the post-published documents (49) and (56), which do not disclose synergistic effects or S6K1-inhibition, and according to which a reduction of more than 50% of chromogranin A is not generally achieved.

4.8 In summary, no common general knowledge existed, which in combination with the disclosure in the patent application could have led the skilled person to the conclusion that everolismus was suitable in the treatment of PNETs. In these circumstances the post-published documents cannot be used to remedy the insufficiency of disclosure (see point 4.2 above). Moreover, as pointed out by the appellants, document (49), and consequently also document (56), do not merely confirm the "study" in paragraphs [0052] and [0053]. Rather they disclose additional information, for example, that the study concerned patients with advanced low to intermediate-grade neuroendocrine tumours (a significant group of which did not even show an increased level of chromogranin A (e.g. 18 of 32 patient in document (49) and 37 of 60 patients in document (56)). No such disclosure can be found in said paragraphs.

4.9 The respondent made reference to points 28 of the decisions T 433/05 and T 801/06. The board agrees with

the statements made in these decisions (see point XVI above). However, for the reasons set out above, the board judges that in the present case no data or plausible technical concept is present in the patent in suit at the relevant date that allows the skilled person to conclude that everolismus is suitable in the treatment of PNETs.

4.10 The respondent also referred to T 609/02 and T 801/10 according to which it was sufficient that the observed effect directly and unambiguously reflected the therapeutic application.

However, as explained above (see point 4.4.1) in the present case no effect was observed. It is merely stated that certain effects may be observed. Moreover, a link between mTOR inhibition and treatment of PNETs was not known in the art.

4.11 Hence, in view of the facts and arguments presented to it, the board comes to the conclusion that the ground under Article 100(b) EPC prejudices the maintenance of the patent in suit as granted.

5. Admission of auxiliary requests 3, 6 and 8

5.1 Auxiliary requests 3 and 8 were filed with the reply to the statements setting out the grounds of appeal. Pursuant to Article 12(1), 12(2) and 12(4), second half-sentence, RPBA, these requests are therefore to be taken into account in the appeal proceedings.

The board has however the power to hold inadmissible requests which could have been presented or were not admitted in the opposition proceedings (Article 12(4), first-half sentence, RPBA).

5.2 The mere fact that a request could have been filed in opposition proceedings is not as such a sufficient reason to hold a request inadmissible (see T 134/11, point 3.3 of the Reasons). In the practice of the boards of appeal, such a request is normally inadmissible in exceptional circumstances, for example, if a fresh case is created, which renders the decision under appeal obsolete and requires the board either to conduct the case anew or to remit it to the opposition division, or in cases where the patent proprietor/ applicant made a deliberate choice to withhold requests which could have overcome objections raised in the first-instance proceedings and filed them only in the appeal.

5.3 In the present case, there is no indication that the respondent deliberately held back any requests in the opposition proceedings. Indeed, it already submitted auxiliary requests, on which a decision was not required as the opposition division rejected the oppositions. Furthermore, auxiliary requests 3 and 8 do not shift the case to such an extent that the board was required to conduct the case anew or remit it to the opposition division. Finally, the board accepts the respondent's argument that auxiliary requests 3 and 8, like the other auxiliary requests filed with the reply to the statements of grounds of appeal, were submitted in response to the newly filed document (75). This document had been submitted by appellant 1 with the statement of grounds of appeal to address the opposition division's concerns with regard to the teaching of document (14) and to further support its objection of lack of novelty and inventive step.

5.4 Hence, given the circumstances, the submission of the respondent's auxiliary requests 3 and 8, which have been filed without delay at the earliest possible stage in the appeal proceedings, are considered to be a normal and legitimate reaction of the respondent to defend the maintenance of the patent in suit. Accordingly, the board decided to admit auxiliary requests 3 and 8 into the proceedings.

5.5 Auxiliary request 6 was filed with letter of 27 October 2017, less than two weeks before the oral proceedings. The respondent justified the late filing with a change in focus and new arguments that were provided with regard to document (75).

5.6 The board does not agree.

Document (75) was filed by appellant 1 with the statement of grounds of appeal to further support its objections of lack of novelty and inventive step. According to the respondent's own admissions its filing gave rise to the filing of all the respondent's auxiliary requests filed with the reply to the statement of grounds of appeal. The respondent therefore clearly recognised the potential importance of said document and acted accordingly. It is not apparent to the board why the filing of auxiliary request 6 would not have been possible at this stage in the proceedings. A change in focus, which could justify the late filing of auxiliary request 6, is not apparent to the board, irrespective of the fact that further arguments had been provided by appellants 1, 2 and 4 in reply to the respondent's submissions of 21 March 2017. In particular, no new arguments had been provided which could have occasioned the limitation "advanced pancreatic neuroendocrine tumour". Finally, the board

concurs with appellant 2 that there is *prima facie* no clear basis for the amendment made in auxiliary request 6. The passages in the application as originally filed relied on by the respondent refer either to a study of everolismus (compound A) in patients with advanced pancreatic tumours after failure of cytotoxic chemotherapy as monotherapy or mTOR inhibitors in general in the treatment of solid tumours, especially advanced solid tumours.

Accordingly, the board decided not to admit auxiliary request 6 into the proceedings.

Auxiliary request 3

6. Sufficiency of disclosure

6.1 Claim 1 of auxiliary request 3 differs from claim 1 of the main request in that everolismus is used in an amount of 5 mg or 10 mg daily in monotherapy. This amendment does not alter the above assessment with regard to sufficiency of disclosure.

6.2 It was additionally argued by the respondent that by simply following the teaching of paragraphs [0054] and [0056], which clearly identified the patients to be treated (i.e. patients with PNETs), the treatments as monotherapy and the dose to be administered, the skilled person would necessarily find that everolismus is suitable in treatment of PNETs.

6.3 The board does not agree.

Sufficiency of disclosure must essentially be established at the priority date based on the information provided in the application in combination

with common general knowledge then available to the skilled person. As set out in point 4 above, this is not the case here. Moreover, according to the respondent's own admission, the paragraphs on which it relied describe trials which had not yet been carried out and had not yet delivered any results. Indeed, the recruitment for a study of everolismus in monotherapy started well after the earliest priority date and the filing date of the patent in suit and results were apparently not available until several years later (see documents (6), (19) and (59)). In the board's judgement, it is not justified to rely on knowledge which was acquired only after the relevant date to be used as a remedy for insufficiency of disclosure.

The board also does not agree with the respondent that the information in paragraphs [0054] and [0056] is sufficiently detailed to allow the skilled person to carry out the study. The factual situation in T 108/09, on which the respondent relied in this context, is quite different, as in the case underlying that decision there was a detailed study protocol in the application as filed and in addition clear instructions as to dose, interval, mode of administration, blood serum level of the compound, composition of the pharmaceutical formulation and indication as to specific ingredients and their concentration (see T 108/09, point 2.2.2 of the Reasons). In the present case, it is not even mentioned whether the administration of 5 or 10 mg of everolismus daily relates to a single dose or multiple doses, let alone any blood serum levels that should be achieved. Furthermore as mentioned before the tumours to be treated were apparently of a particular type (i.e. advanced low- and intermediate-grade pancreatic tumours; see documents (49), (56), (6) or (59)), which

has also not been mentioned in paragraphs [0054] and [0056] of the patent in suit.

6.4 Decision T 715/03 was not concerned with sufficiency of disclosure, but dealt with the question whether the suitability of ziprasidone for the treatment of Tourette's Syndrome (TS) had been made plausible in the framework of inventive step (i.e. whether the technical problem of providing a treatment for TS had been solved). In T 715/03 the inventor himself had announced in an article published several month before the priority date that a study on the suitability of ziprasidone in the treatment of TS was nearing its completion and confirmed in a declaration that he was already aware of the positive results of the study. The board accepted this as an indication for the plausibility of the statements made in the application. Such a specific constellation does not exist in the present case. In particular, there was no indication at all in the prior art that there was an on-going study nearing its completion. The decision T 715/03 therefore does not support the respondent's case.

6.5 Neither can decision T 950/13 support the respondent's case. In this decision sufficiency of disclosure was acknowledged for the suitability of a compound (dasatinib) in the treatment of a particular cancer (chronic myelogenic leukemia (CML)), although no experimental data were provided in the application. It was, however, clearly and unambiguously disclosed that dasatinib was an inhibitor of BRC-ABL kinase, a fact that could be verified. It was furthermore well established in the art that the BRC-ABL oncogene was the single causative abnormality in chronic myelogenic leukemia. BRC-ABL kinase inhibition was therefore seen as a potential way to treat this disease. Finally, the

skilled person was familiar with the fact that CML could indeed be treated by inhibiting BRC-ABL kinase, as it was widely known that imatinib - an effective BRC-ABL kinase inhibitor - had shown excellent clinical results and had been approved for the treatment of CML well before the filing date of the patent application. In other words, the relationship between BRC-ABL kinase inhibition and the claimed therapeutic application had already been established. The analogy to imatinib was also mentioned in the patent application. The board therefore concluded that the application disclosed at least a plausible technical concept, namely that dasatinib based on its functional equivalence to imatinib as a BRC-ABL kinase inhibitor was suitable in the treatment of CML.

In the present case, no such plausible technical concept is apparent for the reasons set out in point 4.6 above.

6.6 The board therefore concludes that the subject-matter of auxiliary request 3 does not meet the requirement of sufficiency of disclosure. For this reason, this request must fail.

Auxiliary request 4

7. Sufficiency of disclosure

7.1 Compared to the claims as granted, claim 1 of auxiliary request 4 limits the amount of everolismus to 10 mg day. This limitation does not change the reasoning concerning sufficiency of disclosure presented in points 4 or 6.3 above.

7.2 The respondent's additional arguments with regard to document (59) (see point XVI above) are not accepted. Document (59) is published almost nine years after the earliest priority date and cannot be used to remedy the lack of sufficiency of disclosure.

Hence, the board concludes that the subject-matter of auxiliary request 4 does not meet the requirement of sufficiency of disclosure. Accordingly, this request must also fail.

Auxiliary requests 5, 7 and 8

8. Sufficiency of disclosure

The amendments made in auxiliary requests 5, 7 and 8 (10 mg in monotherapy; 10 mg in monotherapy of patients with advanced PNETs after failure of cytotoxic chemotherapy; treatment of specific PNETs; see point X above) do not alter the assessment in points 4 or 6.3 above. Indeed, the parties did not submit any arguments specific to these auxiliary requests.

Accordingly, the board concludes that auxiliary requests 5, 7 and 8 must also fail for lack of sufficiency of disclosure.

Further requests

9. Admission of documents (75) to (80)

Having concluded that the requirement of sufficiency of disclosure was not met, a decision on the admission of documents (75) to (80) was not necessary.

10. With regard to the respondent's requests concerning the acceleration of the proceedings and the discussion of T 950/13 (see point XVIII above), reference is made to points 3 and 6.5 above.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The patent is revoked.

The Registrar: The Chairman:

M. Schalow A. Lindner

Decision electronically authenticated